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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,469	03/01/2002	Raymond A. Hui	9793/96 (RDID 01061)	6651

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,469	HUI, RAYMOND A.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) It is required that the title of this application be changed to adequately reflect that the invention relates to the analysis of ecstasy-type drugs.

2) Reference A12 of form PTO-1449 filed May 30, 2002 has been considered but will not be published on the front of any patent issuing from this application for the reason that the citation does not contain a publication date as required by 37 CFR 1.98(b)(5).

3) Citations A15 and A16 of form PTO-1449 filed May 30, 2002, each of which contains citations of *multiple* publications, have not been considered since they fail to provide the information required by 37 CFR 1.98*8b)(5) for *each* publication cited; applicant has further failed to provide a copy of *each* publication cited as required by 37 CFR 1.98(a)0(2))(a). Applicant is reminded of his duty to disclose information material to patentability in accordance with 37 CFR 1.56, particularly subparagraph (a)(2), namely:

"The *closest* information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, *to make sure that any material information contained therein is disclosed to the Office."*

Applicant is advised that the citation of a large number of documents, without a discussion of the relevance of each document to the claimed invention, increases the risk that documents of particular relevance will not be adequately considered by the examiner during prosecution.

4) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6) Claims 17, 18, 31 and 42-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 28 and 40-42 of copending Application No. 10/087,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because "an antibody specific for an ecstasy drug" and "an antibody of claim 17 wherein the ecstasy drug is...MDEA" (claims 17 and 18 of the instant application) encompass "an antibody specific for MDEA" (claim 16 of 10/087,612), i.e. the antibodies of both applications have specificity for MDEA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7) Claims 17, 18 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 of copending Application No. 10/622,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because "an antibody specific for an ecstasy drug" (claim 17 of 10/087,464) and "an antibody of claim 17 wherein the ecstasy drug is...MDEA" (claim 18 of 10/087,464) both encompass "a monoclonal antibody...having greater that 100% cross-reactivity to MDEA" (claim 7 of 10/622,254), i.e. the antibodies of both applications have specificity for MDEA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8) Claims 17, 18, 31 and 42-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 16, 26 and 33-35 of copending Application No. 10/622,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because "an antibody specific for an ecstasy drug" (claim 17 of 10/087,469) and "the antibody of claim 17 wherein the ecstasy drug is...MDEA" (claim 18 of 10/087,469) encompasses "an antibody that preferentially binds MDEA" (claim 14 of 10/622,524), i.e. the antibodies of both applications have specificity for MDEA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10) Claims 1, 14, 15 and 42-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The proviso of claim 1 appears to include definitions of "R^1" which are *not* contained in the earlier appearing definition of "R^1" defined as "-J-M-T"; i.e., "R^1" defined as "-CH_2CN, -$CH_2C{=}CH_2$...or -CH_2CCH" do not fall under the definitions of "-J-M-T". For example the term "R^1" defined as "-CHO" contains neither a moiety corresponding to "J" comprising "1-15 carbon atoms and 0-6 heteroatoms", any of the moieties defined by "M" nor "T" defined as "hydrogen, a hydroxyl,...and a label". See also, page 8, lines 9-29 for definitions of "leaving group" and "protecting group".

b) Claims 14 and 15 are indefinite in not defining the term "TFA" which does not appear in the specification.

c) Claims 42, 45 and 48 are indefinite in not reciting the type/structure of the "analyte" to be detected. Additionally, these claims are indefinite and incomplete for the reason that they fail to define how the "adduct formed by the antibody and the analyte" is to be detected; presumably the use of a tracer or labeled secondary antibody would be required to practice the methods.

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13) Claims 1-30 and 34-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Brynes et al (US 5,101,015).

Brynes et al describe activated methylenedioxy (meth)amphetamine haptens containing a linker between the functional group and the hapten, immunogenic conjugates prepared from the activated haptens, antibodies prepared from the immunogens, and the use of the antibodies in an immunoassay. These descriptions anticipate the activated linker-haptens, immunogens, antibodies and immunoassays of the instant claims. See Brynes et al: col. 7, line 8 – col. 8, line 41. For the activated linker-haptens of instant claims 1 and 4-11 wherein M is –CO-, J is alkylene, and the amine group is protected, see Brynes

et al, col. 7, lines 33-34 wherein M includes alkylene, W is carboxyl, and the amine is protected (col. 8, lines 21-32); see also the structure of col. 7, line 60. The specific methylenedioxy (meth)amphetamine haptens MDA (3,4-methylenedioxyamphetamine) and MDEA (N-ethyl-3,4-methelenedioxyamphetamine) of the instant claims are described by Brynes et al at col. 4, lines 3-4. The immunogenic carriers of instant claim 12 are described at col. 5, lines 11-32 of Brynes et al.

14) Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brynes et al (US 5,101,015).

Brynes et al is applied for the reasons stated in the 35 USC 102(b) rejection above. The packaging of reagents in kit form is an obvious expedient for ease and convenience in assay performance.

15) The following references further show the state of the art:

a) Braun et al (J. Pharm. Sci. (1980), 69(2), 192-195), structures II/– II*p*; these prior art structures are the subset of compounds eliminated by proviso from instant claim 1.

b) Owens et al (US 6,669,937): see the figures.

c) Rouhani et al (US 2003/0207469 A1): see paragraphs [0010] – [0016].

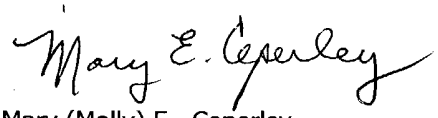
d) McConnell et al (US 2004/0121400 A1): see paragraphs [0026] – [0035].

e) Rubenstein et al (US 4,067,774): see the tables of columns 38 and 39; claim 3; col. 18, lines 18-60.

16) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



September 21, 2004

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641